BIOPESTICIDE REGISTRATION ACTION DOCUMENT

STRAIGHT CHAIN LEPIDOPTERAN PHEROMONES (SCLP)

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

TABLE OF CONTENTS

CHAPTER 1

OVERVIEW OF STRAIGHT CHAIN LEPIDOPTERAN PHEROMONES

I. EXECUTIVE SUMMARY

A. IDENTITY

A pheromone (including identical or substantially similar synthetic compounds) as defined by the Agency is a compound produced by a species which, alone or in combination with other compounds produced by that species, modifies the behavior of other individuals of the same species. Straight Chain Lepidopteran Pheromones (SCLPs) are those produced by a member of the order Lepidoptera, which includes butterflies and moths.

The SCLPs that are addressed in this document fall under the criteria that are in 40 CFR 180.1153, titled Lepidopteran pheromones; exemption from the requirement of a tolerance. The 40 CFR 180.1153 states, "Lepidopteran pheromones that are naturally occurring compounds, or identical or substantially similar synthetic compounds, designated by an unbranched aliphatic chain (between 9 and 18 carbons) ending in an alcohol, aldehyde or acetate functional group and containing up to 3 double bonds in the aliphatic backbone.

B. USE/USAGE

In most cases the SCLPs listed in this document are for manufacturing use products (MPs). These MPs are then formulated into end use products (EPs) which in most cases are used as attractants or for mating disruption for the targeted lepidoteran species.

C. RISK ASSESSMENT

As stated above, the majority of these active ingredients are manufacturing use products, and do not require a food clearance/tolerance. However, straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices and indoor post-harvest treatment in or on all stored food commodities when applied/used at a rate not to exceed 3.5 grams active ingredient (AI)/1,000 square feet/year (equivalent of 150 grams AI/acre/year) in accordance with good agricultural practices use practices [40 CFR 180.1153 (a) & (b)]

In most cases the toxicology and environmental data requirements for these SCLPs product were waived per the OECD publication - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm). This document reports that no risks to human health are expected from the use of lepidopteran pheromones based on the low toxicity in animal testing and the expected low exposure to humans. Furthermore, adverse effects on nontarget organisms are not expected because these pheromones are released in very small quantities in the environment and act on a select group of insects. Appropriate precautionary labeling of end use products will further minimize potential exposure and mitigate risk to nontarget organisms.

The Agency has considered SCLPs in light of relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and determined there will be no unreasonable adverse effects from the use of this product. The Agency is basing its risk management decision regarding the registration of these SCLPs on the known low toxicity of lepidopteran pheromones, the limited exposure to humans, and the precautionary labeling that minimizes exposure and mitigates risk to nontarget organisms. The Agency believes that end use products containing SCLPs can be used without causing unreasonable adverse effects to humans or the environment.

D. DATA GAPS / LABELING RESTRICTIONS

If there are any data gaps and/or labeling restrictions they would be specific to each of the individual SCLP product. Please refer to the following chapters for each individual SCLP product.

II. OVERVIEW

A. ACTIVE INGREDIENT OVERVIEW

The active ingredients addressed under this document are Straight Chain Lepidopteran pheromones. Per 40 CFR 180.1153, the Agency defines lepidopteran pheromones as naturally-occurring compounds, or identical or substantially similar synthetic compounds, designated by an unbranched aliphatic chain (between 9 and 18 carbons) ending in an alcohol, aldehyde or acetate functional group and containing up to 3 double bonds in the aliphatic backbone. Please refer to each individual SCLP chapter for it's specific active ingredient overview.

B. USE PROFILE

The following is information on the proposed uses with an overview of use sites and application methods.

***Type of Pesticide*:** Synthetic semiochemical insect attractant (mating disrupter)

Use Sites: SCLPs are used for manufacturing use and end use products. Please refer to each individual SCLP chapter for the specific uses. This product is for formulation into end use products to be used to control the beet armyworm moth.

***Target Pests*:** Lepidoptera

***Formulation Types*:** Please refer to each individual SCLP chapter for the specific formulation types.

***Method and Rates of Application*:** Please refer to each individual SCLP chapter for the specific method and rates of application.

***Use Practice Limitations*:** Please refer to each individual SCLP chapter for the specific use practice limitation

C. DATA REQUIREMENTS

Please refer to each individual SCLP chapter for the specific data requirements. Historically, the Agency has supported requests for waivers from the requirements of studies/data for acute mammalian toxicity and for non-target organism testing. These data were waived based on the following criteria from the OECD publication - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm): 1) low toxicity in animal testing, 2) expected low exposure to humans, 3) no expected risk to human health, 4) no reported adverse effects during more than 10 years of use as pesticides, and 5) no expected adverse effects to nontarget organisms. Please note that the formulation of these manufacturing use product into food use end use products will require all Tier I toxicity and Tier I nontarget organism data requirements to be addressed for each end use product.

D. REGULATORY HISTORY

The regulatory history of arthropod and SCLPs is as follows. On January 26, 1994 the Agency issued a notice that is was expanding the acreage cut-off for when an Experimental Use Permit (EUP) is required from 10 acres to 250 acres for arthropod pheromones in solid matrix dispensers (OPP-50573; FRL-4755-1). On March 4, 1994 the Agency issued a final rule establishing an exemption from the requirement of a tolerance for residues of from the use of arthropod pheromones in retrievably sized polymeric matrix dispensers with an annual application limitation of 150 grams active ingredient per acre per year (g a.i./A/year) (40 CFR 180.1124). On July 7, 1994 the Agency issued a notice that is was expanding the acreage cut-off for when an EUP is required from 10 acres to 250 acres for arthropod pheromones irrespective of formulation (OPP-50791; FRL-4869-8). On August 30, 1994 the Agency issued a final rule establishing an exemption from the requirement of a tolerance for residues of from the use of lepidopteran pheromones that are naturally occurring compounds, or identical or substantially similar synthetic compounds, designated by an unbranched aliphatic chain (between 9 and 18 carbons) ending in an alcohol, aldehyde or acetate functional group and containing up to 3 double bonds in the aliphatic backbone in or on all raw agricultural commodities with application limitation of 150 g a.i./A/year (40 CFR 180.1153). On August 9, 2006 the 40 CFR 180.1153 was amended to include indoor post-harvest treatment in or on all stored food commodities when applied/used at a rate not to exceed 3.5 grams active ingredient (AI)/1,000 square feet/year (equivalent of 150 grams AI/acre/year) in accordance with good agricultural practices use practices.

F. CLASSIFICATION

All straight-chained lepidopteran pheromone are classified as a biochemical pesticides.

G. FOOD CLEARANCES/TOLERANCES

Manufacturing use products do not require a food clearance/tolerance. Any other uses will require a tolerance. Please refer to each individual SCLP chapter for the specific to determine if there is a tolerance associated with that specific product. However, straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices and indoor post-harvest treatment in or on all stored food commodities when applied/used at a rate not to exceed 3.5 grams active ingredient (AI)/1,000 square feet/year (equivalent of 150 grams AI/acre/year) in accordance with good agricultural practices use practices [40 CFR 180.1153 (a) & (b)].

III. SCIENCE ASSESSMENT

Please refer to each individual SCLP chapter for the specific physical/chemical properties, human health, and environmental assessments.

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

Please refer to each individual SCLP chapter for the specific physical/chemical properties assessment.

B. HUMAN HEALTH ASSESSMENT

Please refer to each individual SCLP chapter for the specific physical/chemical properties assessment.

1. Toxicology Assessment

It is the Agency's position that based on low toxicity in animal testing, and expected low exposure to humans, no risk to human health is expected from the use of lepidopteran pheromones, and consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). The Agency therefore granted the request for waivers for all Tier I mammalian toxicity studies.

2. Dose Response Assessment

Based on all available information for SCLPs, no toxicity endpoints were identified.

3. Dietary Exposure and Risk Characterization

Historically, data waivers have been granted for SCLPs for all mammalian toxicity studies (OPPTS Harmonized Guidelines Series 870). Due to the low toxicity of lepidopteran pheromones in animal testing, and the expected low exposure to humans, no risk to human health is expected from the use of lepidopteran pheromones. Consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for

Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm). Please refer to each individual SCLP chapter for any further characterization specific to the SCLP.

4. Occupational and Residential Exposure

a. Occupational Exposure and Risk Characterization:

The potential for dermal, eye, and inhalation exposures to the pesticide exists for handlers and applicators. Due to the low toxicity of SCLPs in animal testing, no purposeful exposure to human skin, and no repeated inhalation exposure to these active ingredients at toxic levels, worker exposure data on SCLPs are not required. The Agency will require the appropriate signal word and precautionary statements to mitigate any risk from exposure via these routes. Please refer to each individual SCLP chapter for any further characterization specific to the SCLP.

b. Residential, School and Daycare Exposure and Risk Characterization:

No indoor residential, school, or day care uses currently appear on SCLP labels. Although accidental non-dietary exposure at sites where children are present may occur, the health risk is expected to be minimal based on low mammalian toxicity. Please refer to each individual SCLP chapter for any further characterization specific to the SCLP.

5. Drinking Water Exposure and Risk Characterization

Please refer to each individual SCLP chapter for characterization specific to the SCLP.

6. Acute and Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

The Agency has concluded that the potential for SCLP residues are not a dietary hazard to the general population, including infants and children. This decision was based on low toxicity in animal testing, expected low exposure to humans, no expected risk to human health, and no risk from consumption of food containing residues of these pheromones (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). Please refer to each individual SCLP chapter for further characterization specific to the SCLP.

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral and Inhalation

Due to the low toxicity of SCLPs in animal testing, and the expected low exposure to humans, no risk to human health is expected. Consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). Based on this information, the Agency has concluded that aggregate exposure to SCLPs over a lifetime will not pose

appreciable risks to human health. Moreover, the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of SCLPs. The Agency has considered the various routes of exposure and potential risks of the product and determined that the proposed use of the active ingredient does not pose significant risk to all populations, including infants and children.

8. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to SCLPs and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. SCLPs have a non-toxic mode of action. Thus, there is no indication or any evidence to suggest that these biochemical pesticides share any common mechanisms of toxicity with other substances. Therefore, cumulative exposure concerns are not anticipated.

9. Effects on the Immune and Endocrine Systems

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) Amay have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate. Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of SCLPs at this time. The Agency has considered, among other relevant factors, available information concerning whether the active ingredient may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an "endocrine disrupter" produced by these active ingredients. Based on the low potential exposure level associated with the historical uses of these pesticides, the Agency expects no incremental adverse effects to the endocrine or immune systems. Please refer to each individual SCLP chapter for effects on endocrine and immune systems, if any, specific to the SCLP.

CHAPTER 2

Z-9-TETRADECEN-1-YL ACETATE
(PC Code 129109)

C. ENVIRONMENTAL ASSESSMENT

Please refer to each individual SCLP chapter for the specific environmental assessment.

1. Ecological Effects Hazard Assessment

Historically, it has been the Agency's position that adverse effects on non target organisms (mammals, birds, and aquatic organisms) are not expected because these straight-chained lepidopteran pheromones are released in very small amounts to the environment and act on a select group of insects (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). Please refer to each individual SCLP chapter for the specific ecological effects hazard assessment.

2. Environmental Fate and Ground Water Data

Historically, since the Agency has waived, per the registrant's request, the Tier I studies the need for environmental fate and groundwater data [Tier II, 40 CFR 158.690(d)] was not triggered. Please refer to each individual SCLP chapter for the specific physical/chemical properties assessment. Please refer to each individual SCLP chapter for the specific physical/chemical properties assessment. Please refer to each individual SCLP chapter for the specific status as the requirement of environmental fate and ground water data.

3. Ecological Exposure and Risk Characterization

Please refer to each individual SCLP chapter for the specific ecological exposure and risk characterization.

D. EFFICACY DATA

Historically, no efficacy data were required to be submitted to the Agency because no public health uses are involved with the use of SCLPs.

IV. REFERENCES

Lepidopteran Pheromones Fact Sheet issued 09/01. U.S. EPA. http://www.epa.gov/oppbppd1/biopesticides/ingredient/factsheets/factsheet_lep_pheromones.htm

OECD. 2001. OECD Environment, Health, and Safety Publication; Series on Pesticides No.12; Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control. http://www.epa.gov/pesticides/biopesticides/regtools/index.htm

Touhey, J.G. (1990) "A review of the current bases for the United States Environmental Protection Agency's policies for the regulation of pheromones and other semiochemicals, together with a review of the available relevant data which may impact the assessment of risk for these classes of chemicals. Part No. 1, Straight Chain Alcohols, Acetate Esters and Aldehydes". (Unpublished report, 474 pp.)

I. EXECUTIVE SUMMARY

A. IDENTITY

The new active ingredient Z-9-Tetradecen-1-yl acetate is a synthetic straight-chained lepidopteran pheromone. This active ingredient is one of several active ingredients in the end use product Isomate-CM/LR TT which contains 4.34% by weight Z-9-Tetradecen-1-yl acetate. The product chemistry data submitted by the registrant satisfies the requirements for product.

B. USE/USAGE

Z-9-Tetradecen-1-yl acetate is used in the end use product (EP) Isomate-CM/LR TT. The active ingredient is used in an EP for the mating disruption codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*).

C. RISK ASSESSMENT

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices (40 CFR 180.1153).

Toxicology and environmental data requirements for this pheromone product were waived per the OECD publication - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm). This document reports that no risks to human health are expected from the use of lepidopteran pheromones based on the low toxicity in animal testing and the expected low exposure to humans. Furthermore, adverse effects on nontarget organisms are not expected because these pheromones are released in very small quantities in the environment and act on a select group of insects. Appropriate precautionary labeling of end use products will further minimize potential exposure and mitigate risk to nontarget organisms.

The Agency has considered Z-9-Tetradecen-1-yl acetate in light of relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and determined there will be no unreasonable adverse effects from the use of this product. The Agency is basing its risk management decision regarding the registration of Z-9-Tetradecen-1-yl acetate on the known low toxicity of lepidopteran pheromones, the limited exposure to humans, and the precautionary labeling that minimizes exposure and mitigates risk to nontarget organisms. The Agency believes that end use products containing Z-9-Tetradecen-1-yl acetate can be used without causing unreasonable adverse effects to humans or the environment.

D. DATA GAPS / LABELING RESTRICTIONS

There are no data gaps.

II. OVERVIEW

A. ACTIVE INGREDIENT OVERVIEW

Common Name:	Z-9-Tetradecen-1-yl Acetate; or (Z)-9-Tetrdecenyl Acetate
Chemical Name:	Z-9-Tetradecen-1-yl acetate
Chemical Formula:	$C_{16}H_{30}O_2$
Chemical Family:	Insect attractant, repellent and chemosterilant
Trade and Other Names:	Isomate CM/LR TT
CAS Registry Number:	16725-53-4
OPP Chemical Code:	129109
Manufacturer:	Pacific Biocontrol Corporation 14615 NE 13th Court Suite A Vancouver, WA 98685

B. USE PROFILE

The following is information on the proposed uses with an overview of use sites and application methods.

***Type of Pesticide*:** Synthetic semiochemical insect attractant (mating disrupter)

Use Sites: Apples, pears, quince and other pome fruits; peaches prunes, plums, nectarines, cherries and other stone fruits; walnut, pecan and other nut crops.

***Target Pests*:** codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*).

***Formulation Types*:** Liquid

***Method and Rates of Application*:** This active ingredient is part of an end-use product (EP) that contains several other SCLP active ingredients. The application is rate is 300 dispensers per acre. Do not exceed 150 grams active ingredient per acre per year.

***Use Practice Limitations*:** "Do not exceed 150 grams active ingredient per acre per year."

C. ESTIMATED USAGE

The compound , Z-9-Tetradecen-1-yl acetate, is part of an end-use product (EP) that contains several other SCLP active ingredients that act as a mating disruptor codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*).

D. DATA REQUIREMENTS

The Agency has supported the registrant's request for waivers from the requirements of studies/data for acute mammalian toxicity and for non-target organism testing. These data were waived based on the following criteria from the OECD publication - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm): 1) low toxicity in animal testing, 2) expected low exposure to humans, 3) no expected risk to human health, 4) no reported adverse effects during more than 10 years of use as pesticides, and 5) no expected adverse effects to nontarget organisms.

Product analysis data requirements for the end-use product were adequately satisfied.

The data requirements for granting this registration under Section 3(c)(5) of FIFRA have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD). Based on the submitted information, the Agency foresees no unreasonable adverse effects to human health and the environment from the use of Z-9-Tetradecen-1-yl acetate as long as it is used as labeled.

E. REGULATORY HISTORY

On May 8, 2006, the Agency received an application from Pacific Biocontrol Corporation, to register the end use product Isomate-CM/LR TT, containing three new active ingredients, 4.34% by weight Z-9 Tetradecen-1-yl Acetate, 1.05% by weight Z-11-Tetradecen-1-ol, and 1.00% by weight Z-11-Tetradecenal. A notice of receipt of the application for registration of Isomate-CM/LR TT containing three new active ingredients, mentioned above, for an end use product for mating disruption codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*) was published in the Federal Register on July 26, 2006.

F. CLASSIFICATION

Z-9-tetradecen-1-yl acetate is a synthetic straight-chained lepidopteran pheromone and is classified as a biochemical pesticide.

G. FOOD CLEARANCES/TOLERANCES

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices and indoor post-harvest treatment in or on all stored food commodities when applied/used at a rate not to exceed 3.5 grams active ingredient (AI)/1,000 square feet/year (equivalent of 150 grams AI/acre/year) in accordance with good agricultural practices use practices (40 CFR 180.1153).

III. SCIENCE ASSESSMENT

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for Z-9-tetradecen-1-yl acetate have satisfied.

1. Product Identity and Mode of Action

a. Product Identity:

The new active ingredient, Z-9-tetradecen-1-yl acetate, represents 4.34% by weight of the end use product Isomate-CM/LR TT, which is a colorless or light yellow transparent liquid with a mild, fatty-fruity odor.

b. Mode of Action:

Z-9-tetradecen-1-yl acetate is a synthetic lepidopteran pheromone. It is used in the end-use product, Isomate-CM/LR TT, to disrupt mating of codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*) by a non-toxic mode of action.

2. Food Clearances/Tolerances

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices (40 CFR 180.1153).

3. Physical and Chemical Properties Assessment

The physical and chemical characteristics of Z-9-tetradecen-1-yl acetate were submitted to support its registration. These are summarized in Table 1.

Table 1. Product chemistry data requirements			
Guideline No.	**Study**	**Results**	**MRID No.**
151-10 (OPPTS 880.1100)	Product identity	The submitted data satisfy the requirements for product identity.	46832301
151-11 (OPPTS 880.1200)	Manufacturing process	The submitted data satisfy the requirements for the manufacturing process.	46832301
151-12 (OPPTS 880.1400)	Discussion of formation of unintentional ingredients	The submitted data satisfy the requirements for the discussion of the formation of unintentional ingredients.	46832301
151-13 (OPPTS 830.1700)	Analysis of samples	The submitted data satisfy the requirements for the analysis of samples.	46832301
151-15 (OPPTS 830.1750)	Certification of limits	The submitted data satisfy the requirements for the certification of limits.	46832301
151-16 (OPPTS 830.1800)	Analytical method	An acceptable analytical method was submitted.	46832301
Physical/chemical Properties			
63-2 (OPPTS 830.6302)	Color	Colorless or light yellow, transparent	46832301
63-3 (OPPTS 830.6303)	Physical State	Liquid	46832301
63-4 (OPPTS 830.6304)	Odor	Mild, fatty-fruity	46832301
63-5 (OPPTS 830.7200)	Melting point	Not applicable, product is a liquid	46832301
63-6 (OPPTS 830.7220)	Boiling point	116-118 ºC/130 Pa	46832301
63-7 (OPPTS 830.7300)	Density	Specific gravity = 0.875 at 20 ºC	46832301

Table 1. Product chemistry data requirements Cont.			
63-8 (OPPTS 830.7840)	Solubility	Less than 0.1 mg/liter water. Soluble in n-hexane, cyclohexane, benzene, toluene, acetone, methanol, ethanol, chloroform, acetonitrile, pyridine, aniline, DMF, etc. Insoluble in DMSO and ethylene glycol.	46832301
63-9 (OPPTS 830.7950)	Vapor Pressure	$1.71x10^{-2}$ Pa (20ºC)	46832301
63-10 (OPPTS 830.7370)	Dissociation Constant	No dissociation constant	46832301
63-11 (OPPTS 830.7550)	Octanol/water partition coefficient	>6.2 (log P o/w at 20ºC)	46832301
63-12 (OPPTS 830.7000)	pH	5.4	46832301
63-13 (OPPTS 830.6313)	Stability	Stable under normal conditions. Stable under sunlight and hydrolysis exposing water.	46832301
63-14 (OPPTS 830.6314)	Oxidation/reduction	Reaction does not occur under in normal conditions.	46832301
63-15 (OPPTS 830.6315)	Flammability	Flash point = 130ºC	46832301
63-16 (OPPTS 830.6316)	Explodability	No explosion characteristics.	46832301
63-17 (OPPTS 830.6317)	Storage stability	Stable at 5ºC conditions at least 5 years.	46832301
63-18 (OPPTS 830.7100)	Viscosity	5.34 c.s. (20ºC)	46832301
63-19 (OPPTS 830.6319)	Miscibility	Miscible in most common organic solvents except DMSO and ethylene glycol.	46832301
63-20 (OPPTS 830.6320)	Corrosion characteristics	No corrosion characteristics.	46832301
63-21 (OPPTS 830.6321)	Dielectric breakdown voltage	No dielectric breakdown characteristics.	46832301
OPPTS 830.7050	UV/Visible absorption	Not required	

B. HUMAN HEALTH ASSESSMENT

1. Toxicology Assessment

The active ingredient, Z-9-tetradecen-1-yl acetate, is a synthetic lepidopteran pheromone. It is part of the end use product, Isomate-CM/LR TT, which contains several other SCLPs, which is used to disrupt mating of codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis*

limitata), and European leafroller (*Archips rosamus*). The registrant requested waivers for all Tier I mammalian toxicity studies (Guidelines 152-10 through 152-23).

The Agency has previously reviewed the mammalian toxicity data and other information submitted for the registrant's substantially similar products and found it to be adequate for their registration. It is the Agency's position that based on low toxicity in animal testing, and expected low exposure to humans, no risk to human health is expected from the use of lepidopteran pheromones, and consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). The Agency therefore granted the request for waivers for all Tier I mammalian toxicity studies (Table 2).

TABLE 2. Mammalian toxicity data requirements

Guideline No.	Study	Results	MRID No.
152-10 (OPPTS 870.1100)	Acute oral toxicity	Waiver accepted	46832300
152-11 (OPPTS 870.1200)	Acute dermal toxicity	Waiver accepted	46823200
152-12 (OPPTS 870.1300)	Acute inhalation toxicity	Waiver accepted	46823200
152-13 (OPPTS 870.2400)	Primary eye irritation	Waiver accepted	46823200
152-14 (OPPTS 870.2500)	Primary dermal irritation	Waiver accepted	46823200
152-15 (OPPTS 870.2600)	Hypersensitivity	Waiver accepted	46823200
152-16 (885.3400)	Hypersensitivity incidents	Incidents must be reported.	46823200
152-17 (OPPTS 870.5100-5395)	Studies to determine genotoxicity	Waiver accepted	46823200
152-20 (OPPTS 870.3100)	90-Day feeding	Waiver accepted	46823200
152-21 (OPPTS 870.3250)	90-Day dermal	Waiver accepted	46823200
152-22 (OPPTS 870.3465)	90-Day inhalation	Waiver accepted	46823200
152-23 (OPPTS 870.3700)	Teratogenicity	Waiver accepted	46823200

2. Dose Response Assessment

Based on available information, no toxicity endpoints were identified.

3. Dietary Exposure and Risk Characterization

This active ingredient is part of the end-use product Isomate-CM/LR TT. The end use product is a dispenser placed in the lateral branches in the upper third of the trees canopy.

This active ingredient is a straight chain lepidopteran pheromone and is exempt from the requirement of a tolerance under 40 CFR 180.1153, and dietary exposure is not a concern. Data waivers were requested by the registrant for all mammalian toxicity studies (OPPTS Harmonized Guidelines 870/Guidelines 152-10 through 152-23) and were granted. Due to the low toxicity of lepidopteran pheromones in animal testing, and the expected low exposure to humans, no risk to human health is expected from the use of lepidopteran pheromones. Consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm).

4. Occupational and Residential Exposure

a. **Occupational Exposure and Risk Characterization:** The potential for dermal, eye, and inhalation exposures to the pesticide exists for handlers and applicators. Due to the low toxicity of lepidopteran pheromones in animal testing, no purposeful exposure to human skin, and no repeated inhalation exposure to the active ingredient at toxic levels, worker exposure data on Z-9-Tetradecen-1-yl acetate are not required. The Agency will require the appropriate signal word and precautionary statements to mitigate any risk from exposure via these routes.

b. Residential, School and Daycare Exposure and Risk Characterization: No indoor residential, school, or day care uses currently appear on the product label. Although accidental non-dietary exposure at sites where children are present may occur, the health risk is expected to be minimal based on low mammalian toxicity.

5. Drinking Water Exposure and Risk Characterization

This active ingredient is formulated into a dispenser which is placed on the lateral braches in the upper third of the tree canopy. No significant exposure is expected from an accumulation of Z-9-Tetradecen-1-yl acetate in the aquatic environment when it is used according to the precautionary label language.

6. Acute and Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

The Agency has concluded that the potential for Z-9-Tetradecen-1-yl acetate residues is not a dietary hazard to the general population, including infants and children. This decision was based on low toxicity in animal testing, expected low exposure to humans, no expected risk to human health, and no risk from consumption of food containing residues of these pheromones (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)).

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral and Inhalation

Z-9-Tetradecen-1-yl acetate is a synthetic semiochemical that acts via a non-toxic mode of action on a specific insect pest. Due to the low toxicity of lepidopteran pheromones in animal testing, and the expected low exposure to humans, no risk to human health is expected. Consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). Based on this information, the Agency has concluded that aggregate exposure to Z-9-Tetradecen-1-yl acetate over a lifetime will not pose appreciable risks to human health. Moreover, the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of Z-9-Tetradecen-1-yl acetate. The Agency has considered the various routes of exposure and potential risks of the product and determined that the proposed use of the active ingredient does not pose significant risk to all populations, including infants and children.

8. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to Z-9-Tetradecen-1-yl acetate and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. Z-9-Tetradecen-1-yl acetate has a non-toxic mode of action. Thus, there is no indication or any evidence to suggest that this biochemical pesticide shares any common mechanisms of toxicity with other substances. Therefore, cumulative exposure concerns are not anticipated.

9. Effects on the Immune and Endocrine Systems

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate. Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of the active ingredient, Z-9-Tetradecen-1-yl acetate at this time. The Agency has considered, among other relevant factors, available information concerning whether the active ingredient may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an "endocrine disrupter" produced by this

active ingredient. Based on the low potential exposure level associated with the proposed use of this pesticide, the Agency expects no incremental adverse effects to the endocrine or immune systems.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

The registrant requested waivers for the following non-target organism toxicity requirements: Avian Acute Oral Toxicity (GLN 154-6 [OPPTS GLN 850.2100]), Acute Freshwater Fish (GLN 154-8 [OPPTS GLN 850.1075]), Acute Freshwater Invertebrate (GLN 154-9 [OPPTS 850.1010]). The registrant's data for similar straight-chained lepidopteran pheromones show no toxicity issues for non-target organisms. The Agency has previously reviewed the registrant's substantially similar products and found that the non-target organism data/information submitted was adequate to support their registration. It is the Agency's position that adverse effects on non target organisms (mammals, birds, and aquatic organisms) are not expected because these straight-chained lepidopteran pheromones are released in very small amounts to the environment and act on a select group of insects (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). The Agency therefore granted the request for waivers for all non-target organism Tier I (Guidelines 154-6, 154-8 and 154-9) toxicity studies (Table 3). This active ingredient is being registered as part of an end-use product. Non-target organism toxicity testing in not required for end-use product registration. However, it is required for technical grade active ingredient registration. Based on the decision to waive Tier I data requirements, Tier II tests (Guidelines 155-4 through 155-14) and Tier III tests (Guidelines 154-12 through 154-15) were not required.

TABLE 3: Non-target organism toxicity requirements

Guideline	Study	Results	MRID No.
154-6 (OPPTS 850.2100)	Avian acute oral toxicity	Waiver accepted	46823200
154-8 (OPPTS 850.1075)	Freshwater fish LC_{50}	Waiver accepted	46823200
154-9 (OPPTS 850.1010)	Freshwater invertebrate LC_{50}	Waiver accepted	46823200

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data [Tier II, 40 CFR 158.690(d)] was not triggered because the Tier I studies were waived. Risk is minimal due to lack of

exposure, low toxicity, and the use pattern (dispensers placed on lateral branches in the upper third of the tree canopy).

3. Ecological Exposure and Risk Characterization

This active ingredient, Z-9-Tetradecen-1-yl acetate, is part of the end-use product Isomate-CM/LR TT. Z-9-Tetradecen-1-yl acetate is a synthetic lepidopteran pheromone that acts on a specific insect and has a non-toxic mode of action. As a result, no toxicology or environmental fate and effects data were deemed necessary for registration. The waiver requests for submitted data for non-target organisms are summarized in Table 3. In addition, mitigating label language will further reduce the risk to aquatic organisms. The precautionary labeling of Isomate-CM/LR TT is: "For terrestrial uses. Do not apply product directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of this product."

D. EFFICACY DATA

No efficacy data were required to be submitted to the Agency because no public health uses are involved.

IV. RISK MANAGEMENT DECISION

A. DETERMINATION OF ELIGIBILITY

Section 3(c)(5) of FIFRA provides for the unconditional registration of the end use product, Isomate-CM/LR TT, containing the new active ingredient, Z-9-Tetradecen-1-yl actetate, if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria "A" above, products formulated from the use of this manufacturing use product are not expected to cause unreasonable adverse effects when used according to label instructions. Criteria "B" is satisfied by the current label and by data presented in this document. It is believed that Z-9-Tetradecen-1-yl acetate will not cause any unreasonable adverse effect, and is an effective biochemical pesticide for lepidopteran pests, satisfying Criteria "C." Criteria "D" is satisfied in that the pesticide is not expected to cause unreasonable adverse effects when used as described on the label. Therefore, Isomate-CM/LR TT, containing the new active ingredient , Z-9-Tetradecen-1-yl acetate, is eligible for an unconditional registration. The end-use product will be used to control lepidopteran pests in/on agricultural commodities.

B. REGULATORY POSITION

1. Unconditional Registration

This is an unconditional registration. The data submitted are sufficient for unconditional registration of Isomate-CM/LR TT (EPA Reg No.: 53575-31).

2. Tolerance Reassessment

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices and indoor post-harvest treatment in or on all stored food commodities when applied/used at a rate not to exceed 3.5 grams active ingredient (AI)/1,000 square feet/year (equivalent of 150 grams AI/acre/year) in accordance with good agricultural practices use practices (40 CFR 180.1153).

3. Codex Harmonization

There are no Codex harmonization considerations since there is currently no Codex tolerance for residues of Z-9-tetradecen-1-yl acetate.

4. Nonfood Re/Registrations

This is a new active ingredient and, therefore, not the subject of reregistration at this time.

5. Risk Mitigation

There is minimal to negligible potential for risks to non-target organisms (plants and wildlife) or for ground or surface water contamination through the proposed use of this active ingredient, as one of several SCLP active ingredients, is formulated into and end use product which is a dispenser placed on the lateral branches in the upper third of the tree canopy. Further, should any risks occur from occupational exposure to this active ingredient, appropriate mitigating labeling language for aquatic organisms is required.

6. Endangered Species Statement

The Agency has determined that the active ingredient Z-9-Tetradecen-1-yl acetate will not adversely effect threatened or endangered species when used according to label directions.

C. LABELING RATIONALE

It is the Agency's position that the labeling for the end use product Isomate-CM/LR TT containing 4.34% by weight Z-9-Tetradecen-1-yl acetate complies with the current pesticide labeling requirements.

1. Human Health Hazard

a. Worker Protection Standard: This product does not come under the provisions of the Worker Protection Standards (WPS).

b. Non-Worker Protection Standard: There are no non-WPS human health hazard issues.

c. Precautionary Labeling: The Agency has examined the toxicological data base for Z-9-Tetradecen-1-yl acetate and concluded that the precautionary labeling required during this unconditional registration process (i.e. Signal Word, First Aid Statements, and other label statements) adequately mitigates the risks associated with the proposed uses.

d. End Use Product Precautionary Labeling: For Isomate-CM/LR TT, "CAUTION." "Hazard to humans and domestic animals. Avoid contact with skin, eyes, and clothing. Harmful if absorbed through skin. Cause moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco."

e. Spray Drift Advisory No spray drift advisory statement is necessary for this use.

2. Environmental Hazards Labeling

End-Use Product Environmental Hazards Labeling: The following statements are required on the label of this product: "For terrestrial use only. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of this product."

3. Application Rate

300 dispensers per acre (3.82 fl.oz or 98.44 gm a.i. per application). Apply double rate of dispensers to edges of orchard. Do not exceed 150 gm a.i./acre/year (or 457 dispensers) per acre per year.

D. LABELING

ACTIVE INGREDIENT
(E,E)-8,10-Dodecadien-1-ol……..…….38.62%
1-Dodecanol…….6.00%
1-Tetradecanol……..1.40%
Z-11-Tetradecen-1-yl Acetate……..…38.04%
Z-9-Tetradecen-1-yl Acetate……..4.34%
Z-11-Tetradecen-1-ol……1.05%
Z-11-Tetradecenal…….1.00%
Other ingredients……...9.55%

Total…….100.00%

The end use product label shall comply with Agency labeling requirements and must contain the following information:

- Product name
- Ingredient statement
- Registration number
- "Keep out of reach of children"
- Signal word (CAUTION)
- Precautionary statements

V. ACTIONS REQUIRED BY REGISTRANTS

Registrants are required to provide reports of incidents of adverse effects to humans or domestic animals under FIFRA, Section 6(a)(2) and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements, label changes and other responses necessary for the reregistration of the product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. For the same reason, there are also no existing stocks provisions at this time.

VI. APPENDIX A

Table 4 lists the use sites for the product. The label for the product is also attached.

TABLE 4: End Use Registration/Reregistration	
Isomate-CM/LR TT Use sites: Apples, pears, quince and other pome fruits; peaches, prunes, plums, nectarines, cherries and other stone fruits; walnut, pecan and other tree nut crops.	**Official date registered:**

APPENDIX B – REFERENCES

Lepidopteran Pheromones Fact Sheet issued 09/01. U.S. EPA. http://www.epa.gov/oppbppd1/biopesticides/ingredient/factsheets/factsheet_lep_pheromones.htm

Bolan, K.A. Application for Registration of Isomate-CM/LR TT: A Biochemical Mating Disruptant Twin Tube for Codling Moth and Leafroller moth, Volume 2 Product Properties for Biochemical Pesticides. Pacific Biocontrol Corporation, 14615 NE 13th Court, Suite A Vancouver, WA 98685. April 17, 2006. MRID 46832301.

Touhey, J.G. (1990) "A review of the current bases for the United States Environmental Protection Agency's policies for the regulation of pheromones and other semiochemicals, together with a review of the available relevant data which may impact the assessment of risk for these classes of chemicals. Part No. 1, Straight Chain Alcohols, Acetate Esters and Aldehydes". (Unpublished report, 474 pp.)

CHAPTER 3

Z-11-TETRADECEN-1-OL
(PC Code 129021)

I. EXECUTIVE SUMMARY

A. IDENTITY

The new active ingredient Z-11-tetrdecen-1-ol is a synthetic straight-chained lepidopteran pheromone. This active ingredient is one of several straight chain lepidopteran pheromone (SCLP) active ingredients in the end use product Isomate-CM/LR TT which contains 1.05% by weight Z-11-tetrdecen-1-ol. The product chemistry data submitted by the registrant satisfies the requirements for product.

B. USE/USAGE

Z-11-Tetradecen-1-ol is used in the end use product Isomate-CM/LR TT. The active ingredient is used in an EP for the mating disruption codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*).

C. RISK ASSESSMENT

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices (40 CFR 180.1153).

Toxicology and environmental data requirements for this pheromone product were waived per the OECD publication - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm). This document reports that no risks to human health are expected from the use of lepidopteran pheromones based on the low toxicity in animal testing and the expected low exposure to humans. Furthermore, adverse effects on nontarget organisms are not expected because these pheromones are released in very small quantities in the environment and act on a select group of insects. Appropriate precautionary labeling of end use products will further minimize potential exposure and mitigate risk to nontarget organisms.

The Agency has considered Z-11-Tetradecen-1-ol in light of relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and determined there will be no unreasonable adverse effects from the use of this product. The Agency is basing its risk management decision regarding the registration of Z-11-Tetradecen-1-ol on the known low toxicity of lepidopteran pheromones, the limited exposure to humans, and the precautionary labeling that minimizes exposure and mitigates risk to nontarget organisms. The Agency believes that end use products containing Z-11-Tetradecen-1-ol can be used without causing unreasonable adverse effects to humans or the environment.

D. DATA GAPS / LABELING RESTRICTIONS

There are no data gaps.

II. OVERVIEW

A. ACTIVE INGREDIENT OVERVIEW

Common Name:	Z-11-Tetradecen-1-ol; or 11-tetradecen-1-ol (Z)-; or 11-(Z)-Tetradecen-1-ol
Chemical Name:	Z-11-Tetradecen-1-ol
Chemical Formula:	$C_{14}H_{28}O$
Chemical Family:	Insect attractant, repellent and chemosterilant
Trade and Other Names:	Isomate CM/LR TT
CAS Registry Number:	34010-15-6
OPP Chemical Code:	129021
Manufacturer:	Pacific Biocontrol Corporation 14615 NE 13th Court, Suite A Suite A Vancouver, WA 98685

B. USE PROFILE

The following is information on the proposed uses with an overview of use sites and application methods.

***Type of Pesticide*:** Synthetic semiochemical insect attractant (mating disrupter)

Use Sites: Apples, pears, quince and other pome fruits; peaches prunes, plums, nectarines, cherries and other stone fruits; walnut, pecan and other nut crops.

***Target Pests*:** codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*).

***Formulation Types*:** Liquid

***Method and Rates of Application*:** This active ingredient is part of an end-use product (EP) that contains several other SCLP active ingredients. The application is rate is 300 dispensers per acre. Do not exceed 150 grams active ingredient per acre per year.

***Use Practice Limitations*:** "Do not exceed 150 grams active ingredient per acre per year."

C. ESTIMATED USAGE

The compound, Z-11-Tetradecen-1-ol, is part of an end-use product (EP) that contains several other SCLP active ingredients that act as a mating disruptor codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*).

D. DATA REQUIREMENTS

The Agency has supported the registrant's request for waivers from the requirements of studies/data for acute mammalian toxicity and for non-target organism testing. These data were waived based on the following criteria from the OECD publication - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm): 1) low toxicity in animal testing, 2) expected low exposure to humans, 3) no expected risk to human health, 4) no reported adverse effects during more than 10 years of use as pesticides, and 5) no expected adverse effects to nontarget organisms.

Product analysis data requirements for the end-use product were adequately satisfied.

The data requirements for granting this registration under Section 3(c)(5) of FIFRA have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD). Based on the submitted information, the Agency foresees no unreasonable adverse effects to human health and the environment from the use of Z-11-Tetradecen-1-ol as long as it is used as labeled.

E. REGULATORY HISTORY

On May 8, 2006, the Agency received an application from Pacific Biocontrol Corporation, to register the end use product Isomate-CM/LR TT, containing three new active ingredients, 4.34% by weight Z-9 Tetradecen-1-yl Acetate, 1.05% by weight Z-11-Tetradecen-1-ol, and 1.00% by weight Z-11-Tetradecenal. A notice of receipt of the application for registration of Isomate-CM/LR TT containing three new active ingredients, mentioned above, for an end use product for mating disruption codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*) was published in the Federal Register on July 26, 2006.

F. CLASSIFICATION

Z-11-Tetradecen-1-ol is a synthetic straight-chained lepidopteran pheromone and is classified as a biochemical pesticide.

G. FOOD CLEARANCES/TOLERANCES

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices and indoor post-harvest treatment in or on all stored food commodities when applied/used at a rate not to exceed 3.5 grams active ingredient (AI)/1,000 square feet/year (equivalent of 150 grams AI/acre/year) in accordance with good agricultural practices use practices (40 CFR 180.1153).

III. SCIENCE ASSESSMENT

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for Z-11-Tetradecen-1-ol have been satisfied.

1. Product Identity and Mode of Action

a. Product Identity: The new active ingredient, Z-11-Tetradecen-1-ol, represents 1.05% by weight of the end use product Isomate-CM/LR TT, which is a light yellow transparent oily liquid with a mild, fatty-fruity odor.

b. Mode of Action: Z-11-Tetradecen-1-ol is a synthetic lepidopteran pheromone. It is used in the end-use product, Isomate-CM/LR TT, to disrupt mating of codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*) by a non-toxic mode of action. .

2. Food Clearances/Tolerances

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices and indoor post-harvest treatment in or on all stored food commodities when applied/used at a rate not to exceed 3.5 grams active ingredient (AI)/1,000 square feet/year (equivalent of 150 grams AI/acre/year) in accordance with good agricultural practices use practices (40 CFR 180.1153).

3. Physical and Chemical Properties Assessment

The physical and chemical characteristics of Z-11-Tetradecen-1-ol were submitted to support its registration. These are summarized in Table 1.

Table 2. Product chemistry data requirements			
Guideline No.	**Study**	**Results**	**MRID No.**
151-10 (OPPTS 880.1100)	Product identity	The submitted data satisfy the requirements for product identity.	46832301
151-11 (OPPTS 880.1200)	Manufacturing process	The submitted data satisfy the requirements for the manufacturing process.	46832301
151-12 (OPPTS 880.1400)	Discussion of formation of unintentional ingredients	The submitted data satisfy the requirements for the discussion of the formation of unintentional ingredients.	46832301
151-13 (OPPTS 830.1700)	Analysis of samples	The submitted data satisfy the requirements for the analysis of samples.	46832301
151-15 (OPPTS 830.1750)	Certification of limits	The submitted data satisfy the requirements for the certification of limits.	46832301
151-16 (OPPTS 830.1800)	Analytical method	An acceptable analytical method was submitted.	46832301
Physical/chemical Properties for Z-11-Tetradecen-1-ol			
63-2 (OPPTS 830.6302)	Color	light yellow transparent	46832301
63-3 (OPPTS 830.6303)	Physical State	Oily Liquid	46832301
63-4 (OPPTS 830.6304)	Odor	Mild, fatty-fruity	46832301
63-5 (OPPTS 830.7200)	Melting point	Not applicable, product is a liquid	46832301
63-6 (OPPTS 830.7220)	Boiling point	138-140 ºC/520 Pa	46832301
63-7 (OPPTS 830.7300)	Density	Specific gravity = 0.875 at 20 ºC	46832301

Table 1. Product chemistry data requirements Cont.			
63-8 (OPPTS 830.7840)	Solubility	Less than 0.0004g/liter water. Soluble in n-hexane, cyclohexane, benzene, toluene, methylene chloride, chloroform, ethyl ether, acetonitrile, THF, acetone, DMF, etc. Insoluble in DMSO and ethylene glycol.	46832301
63-9 (OPPTS 830.7950)	Vapor Pressure	0.16-0.20 Pa at 20ºC	46832301
63-10 (OPPTS 830.7370)	Dissociation Constant	No dissociation constant	46832301
63-11 (OPPTS 830.7550)	Octanol/water partition coefficient	4.6 (Log Po/w; at 25ºC)	46832301
63-12 (OPPTS 830.7000)	pH	6.0 (at 1000 g/liter of water)	46832301
63-13 (OPPTS 830.6313)	Stability	Stable against sunlight and hydrolysis exposing water.	46832301
63-14 (OPPTS 830.6314)	Oxidation/reduction	Reaction does not occur under normal conditions.	46832301
63-15 (OPPTS 830.6315)	Flammability	Flash point = 130ºC	46832301
63-16 (OPPTS 830.6316)	Explodability	No explosion characteristics.	46832301
63-17 (OPPTS 830.6317)	Storage stability	Stable at 5ºC conditions at least 5 years	46832301
63-18 (OPPTS 830.7100)	Viscosity	5.34 c.s. (20ºC)	46832301
63-19 (OPPTS 830.6319)	Miscibility	Miscible in most common organic solvents except DMSO and ethylene glycol.	46832301
63-20 (OPPTS 830.6320)	Corrosion characteristics	No corrosion characteristics.	46832301
63-21 (OPPTS 830.6321)	Dielectric breakdown voltage	No dielectric breakdown characteristics.	46832301
OPPTS 830.7050	UV/Visible absorption	Not required	

B. HUMAN HEALTH ASSESSMENT

1. Toxicology Assessment

The active ingredient, Z-11-tetradecen-1-ol, is a synthetic lepidopteran pheromone. It is part of the end use product, Isomate-CM/LR TT, which contains several other SCLPs, which is used to disrupt mating of codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*). The registrant requested waivers for all Tier I mammalian

toxicity studies (OPPTS Harmonized Guidelines Series 870/Guidelines 152-10 through 152-23).

The Agency has previously reviewed the mammalian toxicity data and other information submitted for the registrant's substantially similar products and found it to be adequate for their registration. It is the Agency's position that based on low toxicity in animal testing, and expected low exposure to humans, no risk to human health is expected from the use of lepidopteran pheromones, and consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). The Agency therefore granted the request for waivers for all Tier I mammalian toxicity studies (Table 2).

TABLE 2. Mammalian toxicity data requirements

Guideline No.	Study	Results	MRID No.
152-10 (OPPTS 870.1100)	Acute oral toxicity	Waiver accepted	46832300
152-11 (OPPTS 870.1200)	Acute dermal toxicity	Waiver accepted	46823200
152-12 (OPPTS 870.1300)	Acute inhalation toxicity	Waiver accepted	46823200
152-13 (OPPTS 870.2400)	Primary eye irritation	Waiver accepted	46823200
152-14 (OPPTS 870.2500)	Primary dermal irritation	Waiver accepted	46823200
152-15 (OPPTS 870.2600)	Hypersensitivity	Waiver accepted	46823200
152-16 (885.3400)	Hypersensitivity incidents	Incidents must be reported.	46823200
152-17 (OPPTS 870.5100-5395)	Studies to determine genotoxicity	Waiver accepted	46823200
152-20 (OPPTS 870.3100)	90-Day feeding	Waiver accepted	46823200
152-21 (OPPTS 870.3250)	90-Day dermal	Waiver accepted	46823200
152-22 (OPPTS 870.3465)	90-Day inhalation	Waiver accepted	46823200
152-23 (OPPTS 870.3700)	Teratogenicity	Waiver accepted	46823200

2. Dose Response Assessment

Based on available information, no toxicity endpoints were identified.

3. Dietary Exposure and Risk Characterization

This active ingredient is part of the end-use product Isomate-CM/LR TT. The end use product is a dispenser placed in the lateral branches in the upper third of the trees canopy.

This active ingredient is a straight chain lepidopteran pheromone and is exempt from the requirement of a tolerance under 40 CFR 180.1153, and dietary exposure is not a concern. Data waivers were requested by the registrant for all mammalian toxicity studies (Guidelines 152-10 through 152-23) and were granted. Due to the low toxicity of lepidopteran pheromones in animal testing, and the expected low exposure to humans, no risk to human health is expected from the use of lepidopteran pheromones. Consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm).

4. Occupational and Residential Exposure

a. **Occupational Exposure and Risk Characterization:** The potential for dermal, eye, and inhalation exposures to the pesticide exists for handlers and applicators. Due to the low toxicity of lepidopteran pheromones in animal testing, no purposeful exposure to human skin, and no repeated inhalation exposure to the active ingredient at toxic levels, worker exposure data on Z-11-Tetradecen-1-ol are not required. The Agency will require the appropriate signal word and precautionary statements to mitigate any risk from exposure via these routes.

b. Residential, School and Daycare Exposure and Risk Characterization: No indoor residential, school, or day care uses currently appear on the product label. Although accidental non-dietary exposure at sites where children are present may occur, the health risk is expected to be minimal based on low mammalian toxicity.

5. Drinking Water Exposure and Risk Characterization

This active ingredient is formulated into a dispenser which is placed on the lateral braches in the upper third of the tree canopy. No significant exposure is expected from an accumulation of Z-11-Tetradecen-1-ol in the aquatic environment when it is used according to the precautionary label language.

6. Acute and Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

The Agency has concluded that the potential for Z-11-Tetradecen-1-ol residues is not a dietary hazard to the general population, including infants and children. This decision was based on low toxicity in animal testing, expected low exposure to humans, no expected risk to human health, and no risk from consumption of food containing residues of these pheromones (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)).

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral and Inhalation

Z-11-Tetradecen-1-ol is a synthetic semiochemical that acts via a non-toxic mode of action on a specific insect pest. Due to the low toxicity of lepidopteran pheromones in animal testing, and the expected low exposure to humans, no risk to human health is expected. Consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). Based on this information, the Agency has concluded that aggregate exposure to Z-11-Tetradecen-1-ol over a lifetime will not pose appreciable risks to human health. Moreover, the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of Z-11-Tetradecen-1-ol. The Agency has considered the various routes of exposure and potential risks of the product and determined that the proposed use of the active ingredient does not pose significant risk to all populations, including infants and children.

8. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to Z-11-Tetradecen-1-ol and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. Z-11-Tetradecen-1-ol has a non-toxic mode of action. Thus, there is no indication or any evidence to suggest that this biochemical pesticide shares any common mechanisms of toxicity with other substances. Therefore, cumulative exposure concerns are not anticipated.

9. Effects on the Immune and Endocrine Systems

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate. Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of the active ingredient, Z-11-Tetradecen-1-ol at this time. The Agency has considered, among other relevant

factors, available information concerning whether the active ingredient may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an "endocrine disrupter" produced by this active ingredient. Based on the low potential exposure level associated with the proposed use of this pesticide, the Agency expects no incremental adverse effects to the endocrine or immune systems.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

The registrant requested waivers for the following non-target organism toxicity requirements: Avian Acute Oral Toxicity (GLN 154-6 [OPPTS GLN 850.2100]), Acute Freshwater Fish (GLN 154-8 [OPPTS GLN 850.1075]), Acute Freshwater Invertebrate (GLN 154-9 [OPPTS 850.1010]) The registrant's data for similar straight-chained lepidopteran pheromones show no toxicity issues for non-target organisms. The Agency has previously reviewed the registrant's substantially similar products and found that the non-target organism data/information submitted was adequate to support their registration. It is the Agency's position that adverse effects on non target organisms (mammals, birds, and aquatic organisms) are not expected because these straight-chained lepidopteran pheromones are released in very small amounts to the environment and act on a select group of insects (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). The Agency therefore granted the request for waivers for all non-target organism Tier I (Guidelines 154-6, 154-8 and 154-9) toxicity studies (Table 3). This active ingredient is being registered as part of an end-use product. Non-target organism toxicity testing in not required for end-use product registration. However, it is required for technical grade active ingredient registration. Based on the decision to waive Tier I data requirements, Tier II tests (Guidelines 155-4 through 155-14) and Tier III tests (Guidelines 154-12 through 154-15) were not required.

TABLE 3: Non-target organism toxicity requirements

Guideline	Study	Results	MRID No.
154-6 (OPPTS 850.2100)	Avian acute oral toxicity	Waiver accepted	46823200
154-8 (OPPTS 850.1075)	Freshwater fish LC_{50}	Waiver accepted	46823200
154-9 (OPPTS 850.1010)	Freshwater invertebrate LC_{50}	Waiver accepted	46823200

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data [Tier II, 40 CFR 158.690(d)] was not triggered because the Tier I studies were waived. Risk is minimal due to lack of exposure, low toxicity, and the use pattern (dispensers placed on lateral branches in the upper third of the tree canopy).

3. Ecological Exposure and Risk Characterization

This active ingredient, Z-11-Tetradecen-1-ol, is part of the end-use product Isomate-CM/LR TT. Z-11-Tetradecen-1-ol is a synthetic lepidopteran pheromone that acts on a specific insect and has a non-toxic mode of action. As a result, no toxicology or environmental fate and effects data were deemed necessary for registration. The waiver requests for submitted data for non-target organisms are summarized in Table 3. In addition, mitigating label language will further reduce the risk to aquatic organisms. The precautionary labeling of Isomate-CM/LR TT "For terrestrial uses. Do not apply product directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of this product."

D. EFFICACY DATA

No efficacy data were required to be submitted to the Agency because no public health uses are involved.

IV. RISK MANAGEMENT DECISION

A. DETERMINATION OF ELIGIBILITY

Section 3(c)(5) of FIFRA provides for the unconditional registration of the end use product, Isomate-CM/LR TT, containing the new active ingredient, Z-11-Tetradecen-1-ol, if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria "A" above, products formulated from the use of this manufacturing use product are not expected to cause unreasonable adverse effects when used according to label instructions. Criteria "B" is satisfied by the current label and by data presented in this document. It is believed that Z-11-Tetradecen-1-ol will not cause any unreasonable adverse effect, and is an effective biochemical pesticide for lepidopteran pests, satisfying Criteria "C." Criteria "D" is satisfied in that the pesticide is not expected to cause unreasonable adverse effects when used as described on the label. Therefore, Isomate-CM/LR TT, containing the new active ingredient , Z-11-Tetradecen-1-ol, is eligible for an unconditional registration. The end-use product will be used to control lepidopteran pests in/on agricultural commodities.

B. REGULATORY POSITION

1. Unconditional Registration

The data submitted are sufficient for unconditional registration of Isomate-CM/LR TT (EPA Reg No.: 53575-31).

2. Tolerance Reassessment

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices and indoor post-harvest treatment in or on all stored food commodities when applied/used at a rate not to exceed 3.5 grams active ingredient (AI)/1,000 square feet/year (equivalent of 150 grams AI/acre/year) in accordance with good agricultural practices use practices (40 CFR 180.1153).

3. Codex Harmonization

There are no Codex harmonization considerations since there is currently no Codex tolerance for residues of Z-11-Tetradecen-1-ol.

4. Nonfood Re/Registrations

This is a new active ingredient and, therefore, not the subject of reregistration at this time.

5. Risk Mitigation

There is minimal to negligible potential for risks to non-target organisms (plants and wildlife) or for ground or surface water contamination through the proposed use of this active ingredient, as one of several SCLP active ingredients, is formulated into and end use product which is a dispenser placed on the lateral branches in the upper third of the tree canopy. Further, should any risks occur from occupational exposure to this active ingredient, appropriate mitigating labeling language for aquatic organisms is required.

6. Endangered Species Statement

The Agency has determined that the active ingredient Z-11-Tetradecen-1-ol will not adversely effect threatened or endangered species when used according to label directions.

C. LABELING RATIONALE

It is the Agency's position that the labeling for the end use product Isomate-CM/LR TT containing 1.05% by weight Z-11-Tetradecen-1-ol complies with the current pesticide labeling requirements.

1. Human Health Hazard

a. Worker Protection Standard: This product does not come under the provisions of the Worker Protection Standards (WPS).

b. Non-Worker Protection Standard: There are no non-WPS human health hazard issues.

c. Precautionary Labeling: The Agency has examined the toxicological data base for Z-11-Tetradecen-1-ol and concluded that the precautionary labeling required during this unconditional registration process (i.e. Signal Word, First Aid Statements, and other label statements) adequately mitigates the risks associated with the proposed uses.

d. End Use Product Precautionary Labeling: For Isomate-CM/LR TT, "CAUTION." "Hazard to humans and domestic animals. Avoid contact with skin, eyes, and clothing. Harmful if absorbed through skin. Cause moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco."

e. Spray Drift Advisory No spray drift advisory statement is necessary for this use.

2. Environmental Hazards Labeling

End-Use Product Environmental Hazards Labeling: The following statements are required on the label of this product: "For terrestrial use only. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of this product."

3. Application Rate

300 dispensers per acre (3.82 fl.oz or 98.44 gm a.i. per application). Apply double rate of dispensers to edges of orchard. Do not exceed 150 gm a.i./acre/year (or 457 dispensers) per acre per year.

D. LABELING

ACTIVE INGREDIENT
(E,E)-8,10-Dodecadien-1-ol……..…….38.62%
1-Dodecanol…….6.00%
1-Tetradecanol……..1.40%
Z-11-Tetradecen-1-yl Acetate……..…38.04%
Z-9-Tetradecen-1-yl Acetate……..……..4.34%
Z-11-Tetradecen-1-ol……1.05%
Z-11-Tetradecenal…….1.00%
Other ingredients……...9.55%
Total…….100.00%

The end use product label shall comply with Agency labeling requirements and must contain the following information:

- Product name
- Ingredient statement
- Registration number
- "Keep out of reach of children"
- Signal word (CAUTION)
- Precautionary statements

V. ACTIONS REQUIRED BY REGISTRANTS

Registrants are required to provide reports of incidents of adverse effects to humans or domestic animals under FIFRA, Section 6(a)(2) and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements, label changes and other responses necessary for the reregistration of the product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. For the same reason, there are also no existing stocks provisions at this time.

VI. APPENDIX A

Table 4 lists the use sites for the product. The label for the product is also attached.

TABLE 4: End Use Registration/Reregistration	
Isomate-CM/LR TT Use sites: Apples, pears, quince and other pome fruits; peaches, prunes, plums, nectarines, cherries and other stone fruits; walnut, pecan and other tree nut crops.	**Official date registered:**

APPENDIX B – REFERENCES

Lepidopteran Pheromones Fact Sheet issued 09/01. U.S. EPA.
http://www.epa.gov/oppbppd1/biopesticides/ingredient/factsheets/factsheet_lep_pheromones.htm

Bolan, K.A. Application for Registration of Isomate-CM/LR TT: A Biochemical Mating Disruptant Twin Tube for Codling Moth and Leafroller moth, Volume 2 Product Properties for Biochemical Pesticides. Pacific Biocontrol Corporation, 14615 NE 13th Court, Suite A Vancouver, WA 98685. April 17, 2006. MRID 46832301.

Touhey, J.G. (1990) "A review of the current bases for the United States Environmental Protection Agency's policies for the regulation of pheromones and other semiochemicals, together with a review of the available relevant data which may impact the assessment of risk for these classes of chemicals. Part No. 1, Straight Chain Alcohols, Acetate Esters and Aldehydes". (Unpublished report, 474 pp.)

CHAPTER 4

Z-11-TETRADECENAL
(PC Code 120011)

I. EXECUTIVE SUMMARY

A. IDENTITY

The new active ingredient Z-11-Tetradecenal is a synthetic straight-chained lepidopteran pheromone. This active ingredient is one of several straight chain lepidopteran pheromone (SCLP) active ingredients in the end use product Isomate-CM/LR TT which contains 1.05% by weight Z-11-Tetradecenal. The product chemistry data submitted by the registrant satisfies the requirements for product.

B. USE/USAGE

Z-11-Tetradecenal is used in the end use product Isomate-CM/LR TT. The active ingredient is used in an EP for the mating disruption codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*).

C. RISK ASSESSMENT

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices (40 CFR 180.1153).

Toxicology and environmental data requirements for this pheromone product were waived per the OECD publication - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm). This document reports that no risks to human health are expected from the use of lepidopteran pheromones based on the low toxicity in animal testing and the expected low exposure to humans. Furthermore, adverse effects on nontarget organisms are not expected because these pheromones are released in very small quantities in the environment and act on a select group of insects. Appropriate precautionary labeling of end use products will further minimize potential exposure and mitigate risk to nontarget organisms.

The Agency has considered Z-11-Tetradecenal in light of relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and determined there will be no unreasonable adverse effects from the use of this product. The Agency is basing its risk management decision regarding the registration of Z-11-Tetradecenal on the known low toxicity of lepidopteran pheromones, the limited exposure to humans, and the precautionary labeling that minimizes exposure and mitigates risk to nontarget organisms. The Agency believes that end use products containing Z-11-Tetradecenal can be used without causing unreasonable adverse effects to humans or the environment.

D. DATA GAPS / LABELING RESTRICTIONS

There are no data gaps.

II. OVERVIEW

A. ACTIVE INGREDIENT OVERVIEW

Common Name:	Z-11-Tetradecenal or (Z)-11-Tetradeceal; or 11-tetradecal (Z)-
Chemical Name:	Z-11-Tetradecenal
Chemical Formula:	$C_{14}H_{26}O$
Chemical Family:	Insect attractant, repellent and chemosterilant
Trade and Other Names:	Isomate CM/LR TT
CAS Registry Number:	35237-64-0
OPP Chemical Code:	120011
Manufacturer:	Pacific Biocontrol Corporation 14615 NE 13th Court Suite A Vancouver, WA 98685

B. USE PROFILE

The following is information on the proposed uses with an overview of use sites and application methods.

***Type of Pesticide*:** Synthetic semiochemical insect attractant (mating disrupter)

Use Sites: Apples, pears, quince and other pome fruits; peaches prunes, plums, nectarines, cherries and other stone fruits; walnut, pecan and other nut crops.

***Target Pests*:** codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*).

***Formulation Types*:** Liquid

***Method and Rates of Application*:** This active ingredient is part of an end-use product (EP) that contains several other SCLP active ingredients. The application is rate is 300 dispensers per acre. Do not exceed 150 grams active ingredient per acre per year.

***Use Practice Limitations*:** "Do not exceed 150 grams active ingredient per acre per year."

C. ESTIMATED USAGE

The compound, Z-11-Tetradecenal, is part of an end-use product (EP) that contains several other SCLP active ingredients that act as a mating disruptor codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*).

D. DATA REQUIREMENTS

The Agency has supported the registrant's request for waivers from the requirements of studies/data for acute mammalian toxicity and for non-target organism testing. These data were waived based on the following criteria from the OECD publication - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm): 1) low toxicity in animal testing, 2) expected low exposure to humans, 3) no expected risk to human health, 4) no reported adverse effects during more than 10 years of use as pesticides, and 5) no expected adverse effects to nontarget organisms.

Product analysis data requirements for the end-use product were adequately satisfied.

The data requirements for granting this registration under Section 3(c)(5) of FIFRA have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD). Based on the submitted information, the Agency foresees no unreasonable adverse effects to human health and the environment from the use of Z-11-Tetradecenal as long as it is used as labeled.

E. REGULATORY HISTORY

On May 8, 2006, the Agency received an application from Pacific Biocontrol Corporation, to register the end use product Isomate-CM/LR TT, containing three new active ingredients, 4.34% by weight Z-9 Tetradecen-1-yl Acetate, 1.05% by weight Z-11-Tetradecenal, and 1.00% by weight Z-11-Tetradecenal. A notice of receipt of the application for registration of Isomate-CM/LR TT containing three new active ingredients, mentioned above, for an end use product for mating disruption codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*) was published in the Federal Register on July 26, 2006.

F. CLASSIFICATION

Z-11-Tetradecenal is a synthetic straight-chained lepidopteran pheromone and is classified as a biochemical pesticide.

G. FOOD CLEARANCES/TOLERANCES

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices and indoor post-harvest treatment in or on all stored food commodities when applied/used at a rate not to exceed 3.5 grams active ingredient (AI)/1,000 square feet/year (equivalent of 150 grams AI/acre/year) in accordance with good agricultural practices use practices (40 CFR 180.1153).

III. SCIENCE ASSESSMENT

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for Z-11-Tetradecenal have been satisifed.

1. Product Identity and Mode of Action

a. Product Identity: The new active ingredient, Z-11-Tetradecenal, represents 1.00% by weight of the end use product Isomate-CM/LR TT, which is a light yellow transparent oily liquid with a mild, fatty-fruity odor.

b. Mode of Action: Z-11-Tetradecenal is a synthetic lepidopteran pheromone. It is used in the end-use product, Isomate-CM/LR TT, to disrupt mating of codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European leafroller (*Archips rosamus*) by a non-toxic mode of action. .

2. Food Clearances/Tolerances

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices and indoor post-harvest treatment in or on all stored food commodities when applied/used at a rate not to exceed 3.5 grams active ingredient (AI)/1,000 square feet/year (equivalent of 150 grams AI/acre/year) in accordance with good agricultural practices use practices (40 CFR 180.1153).

3. Physical and Chemical Properties Assessment

The physical and chemical characteristics of Z-11-Tetradecenal were submitted to support its registration. These are summarized in Table 1.

Table 3. Product chemistry data requirements			
Guideline No.	**Study**	**Results**	**MRID No.**
151-10 (OPPTS 880.1100)	Product identity	The submitted data satisfy the requirements for product identity.	46832301
151-12 (OPPTS 880.1400)	Discussion of formation of unintentional ingredients	The submitted data satisfy the requirements for the discussion of the formation of unintentional ingredients.	46832301
151-13 (OPPTS 830.1700)	Analysis of samples	The submitted data satisfy the requirements for the analysis of samples.	46832301
151-15 (OPPTS 830.1750)	Certification of limits	The submitted data satisfy the requirements for the certification of limits.	46832301
151-16 (OPPTS 830.1800)	Analytical method	An acceptable analytical method was submitted.	46832301
Physical/chemical Properties for Z-11-Tetradecenal			
63-2 (OPPTS 830.6302)	Color	light yellow transparent	46832301
63-3 (OPPTS 830.6303)	Physical State	Oily Liquid	46832301
63-4 (OPPTS 830.6304)	Odor	Mild, fatty-fruity	46832301
63-5 (OPPTS 830.7200)	Melting point	Not applicable, product is a liquid	46832301
63-6 (OPPTS 830.7220)	Boiling point	116-122 ºC/390 Pa	46832301
63-7 (OPPTS 830.7300)	Density	Specific gravity = 0.848 at 20 ºC	46832301

Table 1. Product chemistry data requirements Cont.			
63-8 (OPPTS 830.7840)	Solubility	Less than 0.004g/liter water. Soluble in n-hexane, cyclohexane, benzene, toluene, methylene chloride, chloroform, ethyl ether, acetonitrile, THF, acetone, DMF, etc. Insoluble in DMSO and ethylene glycol.	46832301
63-9 (OPPTS 830.7950)	Vapor Pressure	2.0-2.6 Pa at 20ºC	46832301
63-10 (OPPTS 830.7370)	Dissociation Constant	No dissociation constant	46832301
63-11 (OPPTS 830.7550)	Octanol/water partition coefficient	More than 4.0 (Log Po/w; at 25ºC)	46832301
63-12 (OPPTS 830.7000)	pH	6.0 (at 1000 g/liter of water)	46832301
63-13 (OPPTS 830.6313)	Stability	Stable against sunlight and hydrolysis exposing water.	46832301
63-14 (OPPTS 830.6314)	Oxidation/reduction	Reaction does not occur in normal conditions.	46832301
63-15 (OPPTS 830.6315)	Flammability	Flash point = 136ºC	46832301
63-16 (OPPTS 830.6316)	Explodability	No explosion characteristics	46832301
63-17 (OPPTS 830.6317)	Storage stability	Stable at 5ºC conditions at least 1 year.	46832301
63-18 (OPPTS 830.7100)	Viscosity	5.34 c.s. (20ºC)	46832301
63-19 (OPPTS 830.6319)	Miscibility	Miscible in most common organic solvents except DMSO and ethylene glycol.	46832301
63-20 (OPPTS 830.6320)	Corrosion characteristics	No corrosion characteristics	46832301
63-21 (OPPTS 830.6321)	Dielectric breakdown voltage	No dielectric breakdown characteristics.	46832301
OPPTS 830.7050	UV/Visible absorption	Not required	

B. HUMAN HEALTH ASSESSMENT

1. Toxicology Assessment

The active ingredient, Z-11-Tetradecenal, is a synthetic lepidopteran pheromone. It is part of the end use product, Isomate-CM/LR TT, which contains several other SCLPs, which is used to disrupt mating of codling moth (*Cydia pomonella*), obliquebanded leafroller (*Choristoneura rosaceana*), pandemis leafroller (*Pandemis pyrusana*), fruittree leafroller (*Archips argyrospilus*), threelined leafroller (*Pandemis limitata*), and European

leafroller (*Archips rosamus*). The registrant requested waivers for all Tier I mammalian toxicity studies (Guidelines 152-10 through 152-23).

The Agency has previously reviewed the mammalian toxicity data and other information submitted for the registrant's substantially similar products and found it to be adequate for their registration. It is the Agency's position that based on low toxicity in animal testing, and expected low exposure to humans, no risk to human health is expected from the use of lepidopteran pheromones, and consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). The Agency therefore granted the request for waivers for all Tier I mammalian toxicity studies (Table 2).

TABLE 2. Mammalian toxicity data requirements

Guideline No.	Study	Results	MRID No.
152-10 (OPPTS 870.1100)	Acute oral toxicity	Waiver accepted	46832300
152-11 (OPPTS 870.1200)	Acute dermal toxicity	Waiver accepted	46823200
152-12 (OPPTS 870.1300)	Acute inhalation toxicity	Waiver accepted	46823200
152-13 (OPPTS 870.2400)	Primary eye irritation	Waiver accepted	46823200
152-14 (OPPTS 870.2500)	Primary dermal irritation	Waiver accepted	46823200
152-15 (OPPTS 870.2600)	Hypersensitivity	Waiver accepted	46823200
152-16 (885.3400)	Hypersensitivity incidents	Incidents must be reported.	46823200
152-17 (OPPTS 870.5100-5395)	Studies to determine genotoxicity	Waiver accepted	46823200
152-20 (OPPTS 870.3100)	90-Day feeding	Waiver accepted	46823200
152-21 (OPPTS 870.3250)	90-Day dermal	Waiver accepted	46823200
152-22 (OPPTS 870.3465)	90-Day inhalation	Waiver accepted	46823200
152-23 (OPPTS 870.3700)	Teratogenicity	Waiver accepted	46823200

2. Dose Response Assessment

Based on available information, no toxicity endpoints were identified.

3. Dietary Exposure and Risk Characterization

This active ingredient is part of the end-use product Isomate-CM/LR TT. The end use product is a dispenser placed in the lateral branches in the upper third of the trees canopy.

This active ingredient is a straight chain lepidopteran pheromone and is exempt from the requirement of a tolerance under 40 CFR 180.1153, and dietary exposure is not a concern. Data waivers were requested by the registrant for all mammalian toxicity studies (OPPTS Harmonized Guidelines Series 870/Guidelines 152-10 through 152-23) and were granted. Due to the low toxicity of lepidopteran pheromones in animal testing, and the expected low exposure to humans, no risk to human health is expected from the use of lepidopteran pheromones. Consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm).

4. Occupational and Residential Exposure

a. **Occupational Exposure and Risk Characterization:** The potential for dermal, eye, and inhalation exposures to the pesticide exists for handlers and applicators. Due to the low toxicity of lepidopteran pheromones in animal testing, no purposeful exposure to human skin, and no repeated inhalation exposure to the active ingredient at toxic levels, worker exposure data on Z-11-Tetradecenal are not required. The Agency will require the appropriate signal word and precautionary statements to mitigate any risk from exposure via these routes.

b. Residential, School and Daycare Exposure and Risk Characterization: No indoor residential, school, or day care uses currently appear on the product label. Although accidental non-dietary exposure at sites where children are present may occur, the health risk is expected to be minimal based on low mammalian toxicity.

5. Drinking Water Exposure and Risk Characterization

This active ingredient is formulated into a dispenser which is placed on the lateral braches in the upper third of the tree canopy. No significant exposure is expected from an accumulation of Z-11-Tetradecenal in the aquatic environment when it is used according to the precautionary label language.

6. Acute and Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

The Agency has concluded that the potential for Z-11-Tetradecenal residues is not a dietary hazard to the general population, including infants and children. This decision was based on low toxicity in animal testing, expected low exposure to humans, no expected risk to human health, and no risk from consumption of food containing residues of these pheromones (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)).

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral and Inhalation

Z-11-Tetradecenal is a synthetic semiochemical that acts via a non-toxic mode of action on a specific insect pest. Due to the low toxicity of lepidopteran pheromones in animal testing, and the expected low exposure to humans, no risk to human health is expected. Consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). Based on this information, the Agency has concluded that aggregate exposure to Z-11-Tetradecenal over a lifetime will not pose appreciable risks to human health. Moreover, the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of Z-11-Tetradecenal. The Agency has considered the various routes of exposure and potential risks of the product and determined that the proposed use of the active ingredient does not pose significant risk to all populations, including infants and children.

8. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to Z-11-Tetradecenal and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. Z-11-Tetradecenal has a non-toxic mode of action. Thus, there is no indication or any evidence to suggest that this biochemical pesticide shares any common mechanisms of toxicity with other substances. Therefore, cumulative exposure concerns are not anticipated.

9. Effects on the Immune and Endocrine Systems

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate. Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of the active ingredient, Z-11-Tetradecenal at this time. The Agency has considered, among other relevant factors, available information concerning whether the active ingredient may have an effect in

humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an "endocrine disrupter" produced by this active ingredient. Based on the low potential exposure level associated with the proposed use of this pesticide, the Agency expects no incremental adverse effects to the endocrine or immune systems.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

The registrant requested waivers for the following non-target organism toxicity requirements: Avian Acute Oral Toxicity (GLN 154-6 [OPPTS GLN 850.2100]), Acute Freshwater Fish (GLN 154-8 [OPPTS GLN 850.1075]), Acute Freshwater Invertebrate (GLN 154-9 [OPPTS 850.1010]) The registrant's data for similar straight-chained lepidopteran pheromones show no toxicity issues for non-target organisms. The Agency has previously reviewed the registrant's substantially similar products and found that the non-target organism data/information submitted was adequate to support their registration. It is the Agency's position that adverse effects on non target organisms (mammals, birds, and aquatic organisms) are not expected because these straight-chained lepidopteran pheromones are released in very small amounts to the environment and act on a select group of insects (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm)). The Agency therefore granted the request for waivers for all non-target organism Tier I (Guidelines 154-6, 154-8 and 154-9) toxicity studies (Table 3). This active ingredient is being registered as part of an end-use product. Non-target organism toxicity testing in not required for end-use product registration. However, it is required for technical grade active ingredient registration. Based on the decision to waive Tier I data requirements, Tier II tests (Guidelines 155-4 through 155-14) and Tier III tests (Guidelines 154-12 through 154-15) were not required.

TABLE 3: Non-target organism toxicity requirements

Guideline	Study	Results	MRID No.
154-6 (OPPTS 850.2100)	Avian acute oral toxicity	Waiver accepted	46823200
154-8 (OPPTS 850.1075)	Freshwater fish LC_{50}	Waiver accepted	46823200
154-9 (OPPTS 850.1010)	Freshwater invertebrate LC_{50}	Waiver accepted	46823200

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data [Tier II, 40 CFR 158.690(d)] was not triggered because the Tier I studies were waived. Risk is minimal due to lack of exposure, low toxicity, and the use pattern (dispensers placed on lateral branches in the upper third of the tree canopy).

3. Ecological Exposure and Risk Characterization

This active ingredient, Z-11-Tetradecenal, is part of the end-use product Isomate-CM/LR TT. Z-11-Tetradecenal is a synthetic lepidopteran pheromone that acts on a specific insect and has a non-toxic mode of action. As a result, no toxicology or environmental fate and effects data were deemed necessary for registration. The waiver requests for submitted data for non-target organisms are summarized in Table 3. In addition, mitigating label language will further reduce the risk to aquatic organisms. The precautionary labeling of Isomate-CM/LR TT "For terrestrial uses. Do not apply product directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of this product."

D. EFFICACY DATA

No efficacy data were required to be submitted to the Agency because no public health uses are involved.

IV. RISK MANAGEMENT DECISION

A. DETERMINATION OF ELIGIBILITY

Section 3(c)(5) of FIFRA provides for the unconditional registration of the end use product, Isomate-CM/LR TT, containing the new active ingredient, Z-11-Tetradecenal, if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria "A" above, products formulated from the use of this manufacturing use product are not expected to cause unreasonable adverse effects when used according to label instructions. Criteria "B" is satisfied by the current label and by data presented in this document. It is believed that Z-11-Tetradecenal will not cause any unreasonable adverse effect, and is an effective biochemical pesticide for lepidopteran pests, satisfying Criteria "C." Criteria "D" is satisfied in that the pesticide is not expected to cause unreasonable adverse effects when used as described on the label. Therefore, Isomate-CM/LR TT, containing the new active ingredient, Z-11-Tetradecenal, is eligible for an unconditional registration. The end-use product will be used to control lepidopteran pests in/on agricultural commodities.

B. REGULATORY POSITION

1. Unconditional Registration

The data submitted are sufficient for unconditional registration of Isomate-CM/LR TT (EPA Reg No.: 53575-31).

2. Tolerance Reassessment

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices and indoor post-harvest treatment in or on all stored food commodities when applied/used at a rate not to exceed 3.5 grams active ingredient (AI)/1,000 square feet/year (equivalent of 150 grams AI/acre/year) in accordance with good agricultural practices use practices (40 CFR 180.1153).

3. Codex Harmonization

There are no Codex harmonization considerations since there is currently no Codex tolerance for residues of Z-11-Tetradecenal.

4. Nonfood Re/Registrations

This is a new active ingredient and, therefore, not the subject of reregistration at this time.

5. Risk Mitigation

There is minimal to negligible potential for risks to non-target organisms (plants and wildlife) or for ground or surface water contamination through the proposed use of this active ingredient, as one of several SCLP active ingredients, is formulated into and end use product which is a dispenser placed on the lateral branches in the upper third of the tree canopy. Further, should any risks occur from occupational exposure to this active ingredient, appropriate mitigating labeling language for aquatic organisms is required.

6. Endangered Species Statement

The Agency has determined that the active ingredient Z-11-Tetradecenal will not adversely effect threatened or endangered species when used according to label directions.

C. LABELING RATIONALE

It is the Agency's position that the labeling for the end use product Isomate-CM/LR TT containing 1.00% by weight Z-11-Tetradecenal complies with the current pesticide labeling requirements.

1. Human Health Hazard

a. Worker Protection Standard: This product does not come under the provisions of the Worker Protection Standards (WPS).

b. Non-Worker Protection Standard: There are no non-WPS human health hazard issues.

c. Precautionary Labeling: The Agency has examined the toxicological data base for Z-11-Tetradecenal and concluded that the precautionary labeling required during this unconditional registration process (i.e. Signal Word, First Aid Statements, and other label statements) adequately mitigates the risks associated with the proposed uses.

d. End Use Product Precautionary Labeling: For Isomate-CM/LR TT, "CAUTION." "Hazard to humans and domestic animals. Avoid contact with skin, eyes, and clothing. Harmful if absorbed through skin. Cause moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco."

e. Spray Drift Advisory No spray drift advisory statement is necessary for this use.

2. Environmental Hazards Labeling

End-Use Product Environmental Hazards Labeling: The following statements are required on the label of this product: "For terrestrial use only. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of this product."

3. Application Rate

300 dispensers per acre (3.82 fl.oz or 98.44 gm a.i. per application). Apply double rate of dispensers to edges of orchard. Do not exceed 150 gm a.i./acre/year (or 457 dispensers) per acre per year.

D. LABELING

ACTIVE INGREDIENT
(E,E)-8,10-Dodecadien-1-ol……..…….38.62%
1-Dodecanol…….6.00%
1-Tetradecanol……..1.40%
Z-11-Tetradecen-1-yl Acetate……..…38.04%
Z-9-Tetradecen-1-yl Acetate……..……..4.34%
Z-11-Tetradecen-1-ol...……1.05%
Z-11-Tetradecenal…….1.00%
Other ingredients……...9.55%
Total…….100.00%

The end use product label shall comply with Agency labeling requirements and must contain the following information:

- Product name
- Ingredient statement
- Registration number
- "Keep out of reach of children"
- Signal word (CAUTION)
- Precautionary statements

V. ACTIONS REQUIRED BY REGISTRANTS

Registrants are required to provide reports of incidents of adverse effects to humans or domestic animals under FIFRA, Section 6(a)(2) and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements, label changes and other responses necessary for the reregistration of the product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. For the same reason, there are also no existing stocks provisions at this time.

VI. APPENDIX A

Table 4 lists the use sites for the product. The label for the product is also attached.

TABLE 4: End Use Registration/Reregistration	
Isomate-CM/LR TT Use sites: Apples, pears, quince and other pome fruits; peaches, prunes, plums, nectarines, cherries and other stone fruits; walnut, pecan and other tree nut crops.	**Official date registered:**

APPENDIX B – REFERENCES

Lepidopteran Pheromones Fact Sheet issued 09/01. U.S. EPA.
http://www.epa.gov/oppbppd1/biopesticides/ingredients/factsheets/factsheet_lep_pheromones.htm

Bolan, K.A. Application for Registration of Isomate-CM/LR TT: A Biochemical Mating Disruptant Twin Tube for Codling Moth and Leafroller moth, Volume 2 Product Properties for Biochemical Pesticides. Pacific Biocontrol Corporation, 14615 NE 13th Court, Suite A Vancouver, WA 98685. April 17, 2006. MRID 46832301.

Touhey, J.G. (1990) "A review of the current bases for the United States Environmental Protection Agency's policies for the regulation of pheromones and other semiochemicals, together with a review of the available relevant data which may impact the assessment of risk for these classes of chemicals. Part No. 1, Straight Chain Alcohols, Acetate Esters and Aldehydes". (Unpublished report, 474 pp.)